FEB 0 4 2002

K012607
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ALLIANCE
MEDICAL CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter: Alliance Medical Corporation
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Phoenix, Arizona 85044

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Contact: Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

Date of preparation: August 10, 2001

Name of device:

Trade name: Alliance Medical Corporation
Reprocessed Hot Biopsy Forceps

Common name: Hot Biopsy Forceps

Classification name: Endoscopic Electrosurgical Unit and Accessories

Manufacturer	Description	Models
Ballard Products	Medinnovation Thermal Option® II	60101, 60104, 60109, 60110, 60121, 60122
Boston Scientific	Microvasive Radial Jaw® 3	1550

Predicate Devices:

K Number	Device Description	Procode
K932266	Symbiosis Disposable Gastro Biopsy Forceps	GEI
K910964	Symbiosis Hot Biopsy Forceps	GEI
K860366	Microvasive Challenger Hot Biopsy Forceps	GEI
K932790	Thermal Option Electric Biopsy Forceps	KGE

Device description: Biopsy forceps are specially designed instruments that can be used to collect tissue during an endoscopic procedure. Biopsy forceps have a flexible shaft that is designed for introduction through a compatible sized endoscopic operating channel. The instruments incorporate a handpiece with loop-shaped handles for opening and closing the collecting jaws.

Reprocessed biopsy forceps include non-electro-surgical (cold)

biopsy forceps without cauterizing function and electrosurgical (hot) biopsy forceps with cauterizing function. This 510(k) applies to electrosurgical (hot) biopsy forceps with cauterizing function.

Intended use: Reprocessed hot biopsy forceps are intended to be used endoscopically to obtain tissue specimens, remove polyps, and cauterize tissue.

Indications statement: Reprocessed hot biopsy forceps are indicated for use to collect tissue in patients requiring histological examination of the gastrointestinal tract, cauterizing of tissue and removal of polyps.

Technological characteristics: The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the reprocessed device(s) and the predicate device(s) have the same materials and product design. The technological characteristics of the reprocessed hot biopsy forceps are the same as those of the legally marketed predicate devices.

Alliance Medical Corporation's reprocessing of hot biopsy forceps includes removal of adherent visible soil and decontamination. Hot biopsy forceps are tested for electrical continuity and for the ability of the jaws to grasp appropriately. Each individual instrument is tested for appropriate function prior to packaging, labeling, and sterilization operations.

Performance data: Performance data demonstrates that Reprocessed Hot Biopsy Forceps perform as originally intended.

Conclusion: In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (Reprocessed Hot Biopsy Forceps) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2002

Mr. Don Selvey
Vice President,Regulatory Affairs
And Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
PHOENIX, ARIZONA 85044

Re: K012607
Trade/Device Name: Reprocessed Hot Biopsy Forceps
Ballard 60101, 60104, 60109, 60110, 60121, 60122
Microvasive 1550
Regulation Number: 21CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: 78 KGE
Dated: November 9, 2001
Received: November 15, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

K012607
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510(k) Number (if known):

Device Name: Alliance Medical Corporation Reprocessed Hot Biopsy Forceps

Indications for Use: Reprocessed Hot Biopsy Forceps are indicated for use to collect tissue in patients requiring histological examination of the gastrointestinal tract, cauterizing of tissue and removal of polyps.

Manufacturer	Description	Models
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Boston Scientific	Microvasive Radial Jaw® 3	1550

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use ____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012607